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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,683	01/22/2002	Lloyd J. Old	L0461/7125	5148

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,683	OLD ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

This application contains claims directed to the following patentably distinct invention: Claim 1-3 are drawn to cancer diagnosis method using SEQ ID NO:18, 20, or, 22, or each of the proteins encoded by the three different nucleic acids. Claim 20 have several different SEQ ID NOs. The specification (note sequence listing) discloses that the different SEQ ID NOs do not have common structures, thus those nucleic acids and the proteins encoded by the nucleic acid fail *In re Harnish* test. Applicant is required under 35 U.S.C. 121 to elect a single invention. Should applicant traverse on the ground that the different SEQ ID NOs are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the different SEQ ID NOs to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

I. Claims 1-3, drawn to method of diagnosing cancer by detection of SEQ ID NO:18 nucleic acid, classified in class 435, subclass 6.

II. Claims 1-3, 7-11 drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:18 nucleic acid, classified in class 435, subclass 7.23.

III. Claims 1-3, drawn to method of diagnosing cancer by detection of SEQ ID NO:20 nucleic acid, classified in class 435, subclass 6.

IV. Claims 1-3, 7-11, drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:20 nucleic acid, classified in class 435, subclass 7.23.

V. Claims 1-3, drawn to method of diagnosing cancer by detection of SEQ ID NO:22 nucleic acid, classified in class 435, subclass 6.

VI. Claims 1-3, 7-11, drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:22 nucleic acid, classified in class 435, subclass 7.23.

VII. Claim 4, drawn to method of diagnosing cancer by detection of SEQ ID NO:32 nucleic acid, classified in class 435, subclass 6.

VIII. Claim 4, drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:32 nucleic acid, classified in class 435, subclass 7.23.

IX. Claim 5, drawn to method of diagnosing cancer by detection of SEQ ID NO:34 nucleic acid, classified in class 435, subclass 6.

X. Claim 5, drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:34 nucleic acid, classified in class 435, subclass 7.23.

XI. Claim 6, drawn to method of diagnosing cancer by detection of SEQ ID NO:34 nucleic acid, classified in class 435, subclass 6.

XII. Claim 6, drawn to method of diagnosing cancer by detection of protein encoded by SEQ ID NO:34 nucleic acid, classified in class 435, subclass 7.23.

XIII. Claims 12-19, 25-28, drawn to pharmaceutical comprising SEQ ID NO:18 nucleic acid or host cell containing said nucleic acid, classified in class 514, subclass 44.

XIV. Claims 12-19, 29-31, 74-78, drawn to pharmaceutical comprising protein encoded by SEQ ID NO:18 nucleic acid, classified in class 514, subclass 2.

XV. Claims 12-19, 25-28, drawn to pharmaceutical comprising SEQ ID NO:20 nucleic acid, or host cell containing said nucleic acid, classified in class 514, subclass 44.

XVI. Claims 12-19, 29-31, 74-78, drawn to pharmaceutical comprising protein encoded by SEQ ID NO:20 nucleic acid, classified in class 514, subclass 44.

XVII. Claims 12-19, 25-28, drawn to pharmaceutical comprising SEQ ID NO:22 nucleic acid, and host cell expressing said nucleic acid, classified in class 514, subclass 44.

XVIII. Claims 12-19, 29-31, 74-78, drawn to pharmaceutical comprising protein encoded by SEQ ID NO:22 nucleic acid, classified in class 514, subclass 2.

XIX. Claims 20-24, 79, 80, drawn to composition comprising antibody to SEQ ID NO:21, classified in class 530, subclass 387.1.

XX. Claims 20-24, 79, 80, drawn to composition comprising antibody to SEQ ID NO:23, classified in class 530, subclass 387.1.

21. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:25, classified in class 530, subclass 387.1.

22. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:27, classified in class 530, subclass 387.1.

23. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:29, classified in class 530, subclass 387.1.

24. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:31, classified in class 530, subclass 387.1.

25. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:35, classified in class 530, subclass 387.1.

26. Claims 20-24, drawn to composition comprising antibody to SEQ ID NO:37, classified in class 530, subclass 387.1.

27. Claims 32-43, drawn to protein array, classified in class 530, subclass 350.

28. Claims 44-49, drawn to nucleic acid array, classified in class 536, subclass 23.1.

29. Claims 50-51, drawn to kit comprising primers, classified in class 536, subclass 23.44.

30. Claims 52-54, drawn to method of cancer treatment with an agent with certain functions, unclassifiable due to the unknown nature of the agent.

31. Claims 55-63, drawn to method of treatment using CTLs transfected with SEQ ID NO:18, classified in class 424, subclass 184.1.

32. Claims 55-63, drawn to method of treatment using CTLs transfected with SEQ ID NO:21, classified in class 424, subclass 184.1.

33. Claims 55-63, drawn to method of treatment using CTLs transfected with SEQ ID NO:22, classified in class 424, subclass 184.1.

34. Claims 64-66, 71-73, 81, 82, drawn to method of treating or diagnosing or monitoring a patient by administering an antibody to a protein encoded by SEQ ID NO:18, classified in class 424, subclass 130.1.

35. Claims 64-66, 71-73, 81, 82, drawn to method of treating or diagnosing or monitoring a patient by administering an antibody to a protein encoded by SEQ ID NO:20, classified in class 424, subclass 130.1.

36. Claims 64-66, 71-73, 81, 82, drawn to method of treating or diagnosing or monitoring a patient by administering an antibody to a protein encoded by SEQ ID NO:22, classified in class 424, subclass 130.1.

37. Claims 67-70, drawn to method of cancer treatment comprising administering SEQ ID NO:18 nucleic acid or host cell containing said nucleic acid, classified in class 514, subclass 44.

38. Claims 67-70, drawn to method of cancer treatment comprising administering protein encoded by SEQ ID NO:18 nucleic acid, classified in class 514, subclass 2.

39. Claims 67-70, drawn to method of cancer treatment comprising administering SEQ ID NO:20 nucleic acid, or host cell containing said nucleic acid, classified in class 514, subclass 44.

40. Claims 67-70, drawn to method of cancer treatment comprising administering protein encoded by SEQ ID NO:20 nucleic acid, classified in class 514, subclass 44.

41. Claims 67-70, drawn to method of cancer treatment comprising administering SEQ ID NO:22 nucleic acid, and host cell expressing said nucleic acid, classified in class 514, subclass 44.

42. Claims 67-70, drawn to method of cancer treatment comprising administering protein encoded by SEQ ID NO:22 nucleic acid, classified in class 514, subclass 2.

43. Claims 79, and 80, drawn to antibody to protein encoded by SEQ ID NO:19 protein, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The method inventions of (I, III, V) and the product invention of group 29 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of group I, III, or V.

The method inventions of (II, IV, VI) and the product invention of groups (XIX, XX, and 43 respectively) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the products as claimed can be used in a materially different process of such as purifying a protein that binds to the antibody.

Inventions VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions uses different reagents in order to accomplish the purpose set out in the preamble.

Inventions XIII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to pharmaceutical comprising different active ingredients with different structures and functions.

Inventions 21-27 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to antibodies binding to different proteins with different structures and functions.

Inventions 28, and 29 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to microarray containing either nucleic acids or proteins, and these two arrays are used for different purposes.

Inventions 30-42 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods that require different active reagents or ingredients for accomplishing the different purpose set out in each of the invention groups.

The inventions of Groups I-43 have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-43 together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group

requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642